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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,533	03/15/2004	Vanessa I. Chinae	200315755-1	1334
22879	7590	09/25/2006		
HEWLETT PACKARD COMPANY P O BOX 272400, 3404 E. HARMONY ROAD INTELLECTUAL PROPERTY ADMINISTRATION FORT COLLINS, CO 80527-2400				
			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,533

Applicant(s)

CHINEA, VANESSA I.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/05 and 4/17/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 10-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/28/05 wherein the specification is amended and claims 8, 11-13, and 20-22 are amended.

Note: Claims 1-24 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a method of dispensing a pharmaceutical, a method of producing pharmaceutical doses, a pharmaceutical, a method of forming a pharmaceutical dose, and fluid ejection devices as set forth in independent claims 1, 4, 6, 10, 16, and 19.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election of Group III (claims 6-9) with traverse filed 4/17/06 is acknowledged. In addition, Applicant's election of the species, a pharmaceutical comprising digoxin and 2-pyrrolidone. The traversal is on the grounds that: (1) the six groups identified may be patentably distinct, but not both independent and distinct as required by 35 USC 121 and (2) while Applicant believes that the six groups identified by the Examiner may be patentably distinct, the Examiner has not provided a reasoned explanation why the invention as claimed are distinct as well as why the invention must be restricted on the basis of either a separate classification, a separate status in the art, or a different field of search. (3) Applicant requests that the Examiner provide authority for restricting an application when the claims appear in the same class/subclass. (4) The Examiner has not established that an undue burden would be required if the

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restriction requirement was not issued or if issued with fewer groups. (5) Applicant is confused as to what species Applicant is required to elected.

Applicant's arguments have been considered, but are found non-persuasive for the reasons set forth below. (a) According to MPEP 803, an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent or distinct. MPEP further discloses that there are two criteria for a proper restriction requirement between patentably distinct inventions. One criteria are that the inventions must be independent or distinct. The other criteria is that there would be a serious burden on the Examiner if a restriction is not made. Thus, since Applicant has inventions directed to a method of dispensing a pharmaceutical, a method of producing pharmaceutical doses, a pharmaceutical, a method of forming a pharmaceutical dose, and fluid ejection devices as set forth in independent claims 1, 4, 6, 10, 16, and 19. Since, for example independent claim 1 does not require the same components to function that are a part of claim 6, then the claims can not only support separate patents, but are distinct over one another.

35 USC121 gives the Examiner the authority to restrict an application having multiple invention. The inventions are distinct from each other if wither or both of the following can be shown: the process for using the product as claimed can be practiced with another materially different product or the product as claimed can be used in a materially different process of using that product (see MPEP 806.05). Thus, for example, the pharmaceutical composition may be used in multiple methods as set forth

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in independent claims 1, 4, 10, 16, and 19. Thus, while inventions may classify in the same class/subclass due to the various limitations present in the claims, a separate search of that art is necessary to determine, for example, whether specific components can be used for a desired method. Hence, it is a burden for the Examiner to repeatedly search the art for multiple methods that would not necessarily utilize the same pharmaceutical composition.

The paragraph containing the wording 'Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper' is a standard form paragraph that sets forth that the inventions were found to be independent or distinct and have a separate status in the art because the subject matter is not limited to a single invention. However, it is noted in MPEP 803 that should Applicant admit that the claims inventions are all obvious over one another, a restriction will not be required.

In regards to the election of species, the Examiner may request an election of species when a claim is generic to patentably distinct species. In the instant invention, the claim (e.g., claim 6) reads on a solution comprising a vehicle and an active pharmaceutical ingredient. A claim such as independent claim 6, for example, reads on vehicle-active ingredients combinations wherein the vehicle is selected from 2-pyrrolidone, hexanediol, sodium xylene sulfonate, ethylene glycol monophenyl ether, an alcohol, DMSO, n-methyl pyrrolidone, water and ethanol, hydroquinone, cyclodextrins, polyethylene glycol 400-600, absolute ethanol, propylene glycol, glycerin, and a

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multitude of others not disclosed by Applicant. Likewise, the active ingredient may be selected from digoxin, a bioactive agent, a non-ionizable low aqueous solubility drug, prednisolone, sulfamethoxazole, reserpine, any solid that is soluble in a given solvent, and a multitude of other ingredients not specifically disclosed by Applicant. As a result, Applicant was asked to identify a species for search purposes from within the elected group which would be used to conduct an initial search of Applicant's invention. If the species was anticipated or rendered obvious by the prior art, the search would end. If the search was neither anticipated nor rendered obvious by the prior art, the search would be expanded to another species and so forth until, either prior art was found or the full scope of the elected invention was searched.

Thus, the restriction requirement is deemed proper and is made FINAL.

Note: The search was not expanded beyond Applicant's elected species because prior art was found which rendered obvious a pharmaceutical composition comprising digoxin and 2-pyrrolidone.

WITHDRAWN CLAIMS

4. Claims 1-5 and 10-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

112 REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-9: Independent claim 6 is ambiguous because if the phrase 'vehicle with predetermined properties'. In particular, it is unclear what predetermined properties Applicant is referring to that are compatible with the instant invention. Since independent claim 6 is ambiguous, all claims depending thereupon are also ambiguous.

Claim 7: The claim as written is ambiguous because of the phrase 'vehicle includes a component that remains after evaporation and that has a low toxicity as listed in ICH Topic Q3C Impurities'. In particular, it is unclear exactly what component/components is/are compatible with the instant invention.

Claim 7: The term "low toxicity" in claim 7, lines 3-4, is a relative term which renders the claim indefinite. The term "low toxicity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

103 REJECTIONS

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US Patent No. 6,294,192).

Patel et al disclose compositions comprising a hydrophobic therapeutic agent and a carrier (see entire document, especially, abstract). In particular, it is disclosed in (column 21, lines 47-52 and column 23, line 65) that digoxin is a possible hydrophobic therapeutic agent. In column 25, lines 14-35, (especially, lines 14-19, 34, and 36-37), it is disclosed that the pharmaceutical composition may optionally contain a solubilizer to enhance the solubility of the hydrophobic therapeutic agent. In addition, Patel et al disclose that possible solubility agents include amides such as 2-pyrrolidone and polyvinylpyrrolidone. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a pharmaceutical composition comprising digoxin and 2-pyrrolidone because Patel et al disclose that a therapeutic agent such as digoxin may be used in combination with a solubilizer such as 2-pyrrolidone. Furthermore, in regards to the active agent, digoxin, having a solubility of at least about 30 mg/ml in the vehicle (2-pyrrolidone), a skilled practitioner in the art would recognize that a compound/composition and its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)); thus, if both Applicant and the prior art disclose the same compound for a particular composition, the properties would be the same.

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9. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardella et al (US Patent No. 4,002,718) in view of Patel et al (US Patent No. 6,294,192).

Gardella et al disclose digoxin solutions (see entire document, especially, abstract). In addition, Gardella et al disclose digoxin solutions containing polyvinylpyrrolidone (see column 4, Example 1). Thus, while Gardella et al disclose various compositions comprising digoxin and polyvinylpyrrolidone, the reference fails to disclose a composition comprising digoxin in combination with 2-pyrrolidone.

Patel et al (see discussion above)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Gardella et al using the teachings of Patel et al and generate a pharmaceutical composition comprising digoxin and 2-pyrrolidone because: (1) Gardella et al disclose various compositions comprising digoxin and polyvinylpyrrolidone. (2) Patel et al disclose that solubilizers such as 2-pyrrolidone and polyvinylpyrrolidone are used in pharmaceutical compositions to enhance the solubility of the hydrophobic therapeutic agent (digoxin). Hence, since Patel et al disclose that 2-pyrrolidone and polyvinylpyrrolidone are both solubilizers, one would be motivated to interchange the solubilizer without drastically affecting the overall properties of the solution since 2-pyrrolidone and polyvinylpyrrolidone are taught as equivalents. Furthermore, in regards to the active agent, digoxin, having a solubility of at least about 30 mg/ml in the vehicle (2-pyrrolidone), a skilled practitioner in the art would recognize that a compound/composition and its properties are inseparable (In re

Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)); thus, if both Applicant and the prior art disclose the same/similar compound for a particular composition, the properties would be the same/similar.

OBJECTION TO THE SPECIFICATION

10. The disclosure is objected to because of the following informalities: the disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Note: Applicant's attention is directed to page 8, lines 27, 28, and 30 of the specification which contains websites.

Appropriate correction is required.

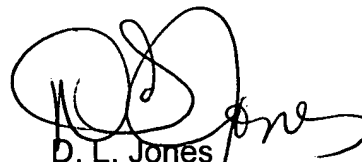
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

September 14, 2006